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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,295	08/23/2001	Stephen C. Knight	VEK-001.01	1054

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FOLEY HOAG, LLP	PORTER, RACHEL L
PATENT GROUP, WORLD TRADE CENTER WEST	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	09/938,295	KNIGHT, STEPHEN C.
Office Action Summary	Examiner	Art Unit	
	RACHEL L. PORTER	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>9/12/08</u>.

2a) ☒ This action is **FINAL**.   2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>2-4,9-12,17 and 19-44</u> is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>2-4,9-12,17 and 19-44</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a) ☐ All   b) ☐ Some * c) ☐ None of:

       1. ☐ Certified copies of the priority documents have been received.

       2. ☐ Certified copies of the priority documents have been received in Application No. _____.

       3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1.   This communication is in response to the amendment filed 9/12/08. Claims 2-

4,9-12,17 and 19-44 are pending.

Claim Rejections - 35 USC § 102

2.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by
> another filed in the United States before the invention by the applicant for patent or (2) a patent
> granted on an application for patent by another filed in the United States before the invention by the
> applicant for patent, except that an international application filed under the treaty defined in section
> 351(a) shall have the effects for purposes of this subsection of an application filed in the United States
> only if the international application designated the United States and was published under Article 21(2)
> of such treaty in the English language.

3.   Claims 34-44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by

Michelson (US 2002/0002474 A1).

Claims 34-44 have been copied by applicant directly from (US 2002/0002474 A1) to

prematurely evoke interference. Therefore, claims 34-44 are clearly anticipated by

claims 22-32 of the Michelson publication.

Claim Rejections - 35 USC § 103

4.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5.   Claims 2-4, 9-12, and 17, 19-33 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Michelson et al (US 2002/0002474 A1) in view of Reddy et al (WO

01/93160 A1)

[claim 17] The limitations of amended claim 17 are addressed by the rejection of claims

19 and 23, and incorporated herein.

[claim 19] Michelson discloses a computer system for recruiting a patient into a clinical

trial, the system comprising components configured as at least:

 a server which: (par. 180)

-    requests patient-specific data from the patient, the patient-specific data

     requested including clinical trial eligibility data; (par. 80-82)

-    collects the patient-specific data from the patient; and (par. 82-83, 90)

-    send match result data to the patient; (par. 167-168)

a matcher responsive to the patient's clinical trial eligibility data and to trial-specific

criteria corresponding to the clinical trial to:

-    determine whether a match exists between the patient and the clinical trial; (par.

     83, and par. 166-167)

   generate the match result data; and (167-168)

      Michelson discusses the exchange of data in a secure environment among

sponsors and investigators (par. 88). Michelson further discloses an Internet

implemented system that uses a plurality of computers/databases, and but does not

expressly disclose a system including a security layer.

Reddy discloses a clinical trials management system including a security layer
(Figures 6-7) which:

-    prevents direct communication between the server and the other workstations ;

      and receives the patient-specific data from the server;. (pg.16, line 7-13; pg. 17,

      lines 5-32   )

The security layer disclosed by Reddy separates network server (e.g. the Internet

server) and from the workstations. Furthermore patient data and secure transactions

pass through the security layer (e.g. prevent direct communication b/n the server and

the matcher). (pg.16, line 7-13; pg. 17, lines 5-32   ) At the time of the applicant's

invention, it would have been obvious to one of ordinary skill in the art to modify the

system/method of Michelson with the teaching of Reddy to include an added security

layer. As suggested by Reddy, one would have been motivated to include this feature

to prevent unauthorized user access (page 17, lines 5-8).

[claim 2] Michelson discloses system of claim 19, wherein the server communicates

with the patient through a patient interface comprises an HTML-encoded web page.

(par. 80, 89-91 –Internet implementation, webpage, Figures 6A-N)

[claim 3] Michelson discloses the system of claim 19, further comprising a patient

database in which patient-specific data is stored (par. 80-83; Figure 1B)

[claim 4] Michelson teaches the system of claim 19, further comprising a clinical trial database, in which the set of trial specific criteria is stored (par. 88, par. 162-170, Figure 1A-1B)

[claim 9] Michelson discloses the system of claim 19, wherein the patient-specific data comprises answers to a questionnaire. (par. 80-83 ; Figures 1A; 15A-E)

[claim 10] Michelson discloses a system configured to send at least a portion of the patient-specific data to the clinical trial. (Figure 15E; par. 83)

[claim 11] Michelson teaches the system of claim 19, wherein the match result data comprises clinical trial at least one of clinical contact and location information, and the server is configured to send match data to the patient. (Figure 14; par. 167-169)

[claim 12] Michelson discloses a system wherein the patient-specific data comprises at least one of disease of concern, demographic data, concomitant diseases, and medications. (Figures 15A-E)

[Claim 20] Michelson discloses the system of claim 19, wherein the system comprises at least two computers. (pars. 80-82)

[claim 21] Michelson and Reddy the system of claim 20 as explained in the rejection of claim 1, and 20. Furthermore, Reddy discloses a system wherein the security layer runs on one of the computers, and the matcher runs on another computer. (Figures 9-11; col. 14, lines 17-48) At the time of the applicant's invention, it would have been

obvious to one of ordinary skill in the art to modify the system of Michelson with the

teaching of Reddy for the reason provided in the rejection of claim 19.

[claims 22, 32]   Michelson discloses the system of claim 3 as explained in the rejection

of claim 3. Michelson further discloses sending the patient-specific data to the patient

database for storage only after the system determines whether a match exists between

the patient and the clinical trial. (Figure 1B; par. 82-83, 168)

Michelson discusses the exchange of data in a secure environment among

system users. (par. 88) Michelson further discloses an Internet implemented system

that uses a plurality of computers/databases, and but does not expressly disclose a

system including a security layer. Reddy discloses a system including a security layer

(Figures 6-7) which prevents direct communication between the server and the other

workstations and receives the patient-specific data from the server (pg.16, line 7-13; pg.

17, lines 5-32)The security layer disclosed by Reddy separates network server and

from the workstations. Furthermore patient data and secure transactions pass through

the security layer (e.g. prevent direct communication b/n the server and the matcher).

(pg.16, line 7-13; pg. 17, lines 5-32)

At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the system/method of Michelson with the teaching of

Reddy to include an added security layer. As suggested by Reddy, one would have

been motivated to include this feature to prevent unauthorized user access (page 17,

lines, 29-32).

[claim 23] Michelson discloses a method of determining whether a patient is a candidate for a clinical trial, comprising:

- serving a questionnaire from a server to a patient through a patient interface; (par. 80-83 ; Figures 1A; 15A-E)
- receiving at the server patient eligibility data submitted by the patient in response to the questionnaire; (par. 80,82-83, 89-91, Fig. 6A-N)
- sending the patient eligibility data from the server; (par. 80-83, 89-91, Fig. 1B)
- sending the patient eligibility data to a matcher; (par. 80-83, 89-91, Fig. 1B)

in the matcher:

- determining whether a match exists between the patient and the clinical trial by comparing the patient eligibility data to a set of trial criteria specific for the clinical trial; and (par. 166-167)
- returning match result information; (par. 167-168)
- sending to the server the match result information; and (par. 167-168)
- serving to the patient through the patient interface the match result information thus sent to the server. (par. 170)

Michelson discusses the exchange of data in a secure environment among system users. (par. 88) Michelson further discloses an Internet implemented system that uses a plurality of computers/databases, and but does not expressly disclose a system including a security layer. Reddy discloses a system including a security layer (Figures 6-7) which prevents direct communication between the server and the other

workstations and receives the patient-specific data from the server (pg.16, line 7-13; pg.

17, lines 5-32)The security layer disclosed by Reddy separates network server and

from the workstations. Furthermore patient data and secure transactions pass through

the security layer (e.g. prevent direct communication b/n the server and the matcher).

(pg.16, line 7-13; pg. 17, lines 5-32)

      At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the system/method of Michelson with the teaching of

Reddy to include an added security layer. As suggested by Reddy, one would have

been motivated to include this feature to prevent unauthorized user access (page 17,

lines, 29-32).

[claim 24] Michelson discloses a method, further comprising serving at least one of

clinical trial contact and location information to the patient through the patient interface.

(par. 169)

[claim 25]   Michelson discloses a method further comprising serving a registration

questionnaire to the patient through the patient interface after a match has been

determined to exist between the patient and the clinical trial. (par. 168)

[claim 26] Michelson discloses a method further comprising receiving a set of

registration information from the patient. (par. 168)

[claim 27]   Michelson discloses a method further comprising adding the registration information to a patient database. (par. 168; Figure 24—subject database)

[claim 28] Michelson discloses a method further comprising sending at least part of the set of registration information to the clinical trial. (par. 169-170)

[claim 29] Michelson disclose a method further comprising comparing, in the matcher, the patient eligibility data to a second set of trial criteria and determining whether a match continues to exist between the patient and the clinical trial. (par. 169, 172)

 [claim 30]   Michelson and Reddy the system of claim 23 as explained in the rejection of claim 23.   Michelson discloses a system comprising at least two computers, (pars. 80-82), but does not specifically disclose a security layer.   Reddy discloses a system wherein the security layer runs on one of the computers, and the matcher runs on another computer. (Figures 6-7; pg.16, line 7-13; pg. 17, lines 5-32) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Michelson with the teaching of Reddy for the reason provided in the rejection of claim 19.

[claim 31]   Michelson discloses a method of determining whether a patient is a candidate for a clinical trial, comprising:

- serving a first questionnaire from a server to a patient through a patient interface; (par. 80-83 ; Figures 1A; 15A-E)

- receiving at the server a first set of patient eligibility data submitted by the patient in response to the first questionnaire; (par. 80,82-83, 89-91, Fig. 6A-N)

- sending the first set of patient eligibility data from the server; (par. 80-83, 89-91, Fig. 1B)

- sending the first set of patient eligibility data from the security layer to a matcher; (par. 80-83, 89-91, Fig. 1B)

in the matcher:

- determining whether a match exists between the patient and the plurality of clinical trials by comparing the first set of patient eligibility data to a set of generic trial criteria generic to a plurality of clinical trials; and (par. 166-167)

- returning generic match result information; (par.166-167))

- if a match exists between the patient and the plurality of clinical trials:

    o serving a second questionnaire from the server to the patient through the patient interface; (par. 168)

    o receiving at the server a second set of patient eligibility data submitted by the patient in response to the second questionnaire; (par. 168-169)

    o sending the second set of patient eligibility data from the server (par. 168-169)

    o sending the second set of patient eligibility data ; (par. 168-169)

in the matcher:

- determining whether a match exists between the patient and the one clinical trial by comparing the second set of patient eligibility data to a set of specific trial criteria specific to one of the plurality of clinical trials; and (par. 169, 172)

- returning specific match result information; (par. 169-170)

- if a match exists between the patient and the one clinical trial:

  o sending information about the one clinical trial ; and (par. 169-170)

  o serving the clinical trial information to the patient through the patient interface. (par. 169-170)

Michelson discusses the exchange of data in a secure environment among system users. (par. 88). Michelson further discloses an Internet implemented system that uses a plurality of computers/databases, and but does not expressly disclose a system including a security layer.

Reddy discloses a system including a security layer (Figures 6-7) which prevents direct communication between the server and the other workstations and receives the patient-specific data from the server (pg.16, line 7-13; pg. 17, lines 5-32).
The security layer disclosed by Reddy separates network server (e.g. the Internet server) and from the workstations. Furthermore patient data and secure transactions pass through the security layer (e.g. prevent direct communication b/n the server and the matcher). (Figures 6-7; pg.16, line 7-13; pg. 17, lines 5-32) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Michelson with the teaching of Reddy to include an added

security layer. As suggested by Reddy, one would have been motivated to include this

feature to prevent unauthorized user access (pg.16, line 7-13; pg. 17, lines 5-32).

[claims 33]   Michelson discloses the system of claim 19 as explained in the rejection of

claim 3. Michelson further discloses sending the patients clinical trial eligibility data, but

not other data to matcher. (Figure 1B; par. 82-83, 168)

       Michelson discusses the exchange of data in a secure environment among

system users. (par. 88). Michelson further discloses an Internet implemented system

that uses a plurality of computers/databases, and but does not expressly disclose a

system including a security layer. Reddy discloses a system including a security layer

(Figures 6-7) which prevents direct communication between the server and the other

workstations and receives the patient-specific data from the server (pg.16, line 7-13; pg.

17, lines 5-32)The security layer disclosed by Reddy separates network server and

from the workstations. Furthermore patient data and secure transactions pass through

the security layer (e.g. prevent direct communication b/n the server and the matcher).

(pg.16, line 7-13; pg. 17, lines 5-32)

       At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the system/method of Michelson with the teaching of

Reddy to include an added security layer. As suggested by Reddy, one would have

been motivated to include this feature to prevent unauthorized user access (page 17,

lines, 29-32).

Response to Arguments

6.   Applicant's arguments filed 9/12/08 have been fully considered but they are not persuasive.

(A)   Applicant argues that claims 34-44 are not anticipated by Michelson et al (US 2002/0002474) because the subject matter is not supported Michelson's provisional, while the subject matter is supported by the applicant's provisional.

In response, the Examiner respectfully disagrees the Applicant's statement that the Michelson provisional does not support the claims. As to applicant's assertion that the Michelson provisional does not describe patient interaction or communication using a computer, the Applicant has provided examples from the provisional application (see page 8, first and second paragraphs) which describe website access to the general public, and provide patients a chance to interact with other patient and investigators. The Michelson provisional further describes an additional security layer which allows communication with patients and investigators. (Page 9, lines 1-3)

It should be noted that the non-provisional application need not be verbatim copy of the provisional. Furthermore, the current rejection is based upon Michelson et al (US 2002/0002474 A1).

Also, while the Applicant's newly added claims 34-44 might be supported by the Applicant's specification, they also represent a shift in the scope of the originally presented invention.

(B)   Applicant argues that Michelson's teaches away from the security layer.

In response, the Examiner respectfully disagrees with applicant's assertion that Michelson teaches away from "a security layer." Michelson discloses both in the provisional (pgs. 8-9) and in the US 200/0002474 (par. 80-83,185) discloses tier access for security purposes. Michelson also provides an explanation of a layering system in the inventive system. (Figure 3- provisional)

However, the Reddy reference was relied upon to disclose the claimed security layer argued by applicant.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(C)   Applicant argues on page 15 of the 9/12/08 response, applicant argues that the instant invention of claim 17 is distinct from the Michelson invention because "the claim specifies that registration occurs *after* clinical trial criteria have been determined to be satisfied."

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "registration occurs *after* clinical trial criteria have been determined to be satisfied") are not recited in the rejected claim(s). Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, the current claim language fails to describe or recite the details of registration process. In particular, there is nothing in the current claim language that explains what steps occur when a patient is "registered" with the system.   Claim 17 describes the exchange of a plurality of "patient-specific" information. The patient is already linked to the system and in system server.

(D)   Applicant argues that Michelson does not disclose a multi-step questionnaire process to screen for clinical trial participants, as claimed in claim 31.

In response, the Examiner respectfully disagrees. The Michelson provisional discloses a multi-step screening process. (pg. 9, par. 1-4 of Provisional application) Moreover, the Michelson reference which was relied upon for the rejection discloses a multiple step screening process to match individuals to clinical trials (Figure 20, par. 168-170, 172).

Conclusion

7.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to RACHEL L. PORTER whose telephone number is

(571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax

phone number for the organization where this application or proceeding is assigned is

571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626